

**K200749 CUBEScan BioCon-900S**May 19, 2020  
57 days to decisionK200749 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k200749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 23, 2020
Decision date	May 19, 2020
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mcube Technology Co., Ltd.</b>
Location	Flintville, TN, US
Contact	Hye-Ri Choi
510(k) history	6 submissions · 6 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200749/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026